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**UNITED STATES DISTRICT COURT**

**DISTRICT OF NEVADA**

PHARMA TECH SOLUTIONS, INC. and  
DECISION IT CORP.,

Plaintiffs,

vs.

LIFESCAN, INC., LIFESCAN SCOTLAND,  
LTD. and JOHNSON AND JOHNSON,

Defendants.

Case No. 2:16-cv-00564-RFB-PAL

**DEFENDANTS' MOTION TO DISMISS  
THE COMPLAINT UNDER RULE 12(b)(6)**

1 Defendants LifeScan Inc., LifeScan Scotland, Ltd. and Johnson & Johnson (collectively,  
2 “LifeScan”) move to dismiss this case under Federal Rule of Civil Procedure 12(b)(6) based on the  
3 Supreme Court’s decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v.*  
4 *Twombly*, 550 U.S. 544 (2007). This motion is supported by the following Memorandum of Points  
5 and Authorities, the Declaration of Anthony DeCinque and the exhibits to that declaration.

6  
7 Dated: August 15, 2016

8 SNELL & WILMER L.L.P.

9 /s/ Chad R. Fears

10 Chad R. Fears

Kelly R. Evans

11 PATTERSON BELKNAP WEBB & TYLER LLP

12 Gregory Diskant

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17 *LifeScan Scotland, Ltd.; and Johnson & Johnson*

1 **MEMORANDUM OF POINTS AND AUTHORITIES**

2 This is an action for patent infringement brought against LifeScan, a worldwide leader in  
 3 glucose monitoring devices, by Pharma Tech Solutions, Inc. and Decision IT Corp. (collectively,  
 4 “Pharma Tech”). Pharma Tech Solutions, Inc. and its corporate parent, Decision Diagnostics, Inc.  
 5 (“DDI”), have been in previous litigation against LifeScan over their unsuccessful effort to enter the  
 6 diabetes monitoring business. Having failed in the marketplace, DDI’s business strategy has  
 7 changed. As the previous litigation was coming to an end, according to public documents, DDI  
 8 purchased the patents in suit in this case for \$250,000, apparently for the purpose of suing LifeScan.  
 9 The patents are expired and are worthless except as a premise for meritless litigation. Based on its  
 10 \$250,000 investment, Pharma Tech claims that LifeScan owes it damages in the astounding sum of  
 11 \$400–\$700 million. *See* Cplt. (ECF No. 1), p.5.

12 Rather than allowing Pharma Tech to turn its baseless Complaint into an expensive and time-  
 13 consuming litigation, the Court is empowered to dismiss it now. Pharma Tech has not alleged a  
 14 plausible basis for its claim. Under *Iqbal*, 556 U.S. 662, and *Twombly*, 550 U.S. 544, which are  
 15 fully applicable to patent litigation, the Complaint should be dismissed because it does not provide a  
 16 plausible basis for Pharm Tech’s allegations that LifeScan’s OneTouch Ultra meters and test strips  
 17 infringe U.S. Patent Nos. 6,153,069 (the ‘069 patent) and 6,413,411 (the ‘411 patent).

18 The claims of the ‘069 and ‘411 patents are extremely narrow and are not practiced by any  
 19 commercial product. They require the use of a diabetes test meter that creates and compares  
 20 separate measurements of *analyte (e.g., glucose) concentration*. The OneTouch system does not do  
 21 that. Instead, it takes and compares separate measurements of *electric current*. Claim charts that are  
 22 exhibits to the Complaint contradict the Complaint’s allegations and confirm this. Pharma Tech has  
 23 pleaded itself out of court.

24 The difference between comparing *concentrations* and *currents* may seem technical and  
 25 esoteric, but that difference is essential to Pharma Tech’s ability to pursue this litigation. As the  
 26 ‘069 and ‘411 patents explain, electric current is proportional to glucose concentration in a glucose  
 27 measurement system, but it is not the same thing. The ‘069 and ‘411 patents cover only systems that  
 28 compare glucose concentration, not ones (like the LifeScan system) that compare electric currents.

1 Indeed, during prosecution of the ‘069 and ‘411 patents, the applicants told the U.S. Patent Office  
2 and the public that their invention is novel, and unlike prior glucose measurement systems, precisely  
3 because it requires comparing analyte concentration, not electric current. Because of this  
4 prosecution history, Pharma Tech must show that LifeScan’s system compares analyte  
5 concentrations, not currents. But, as discussed below, Pharma Tech’s own Complaint shows that  
6 LifeScan’s system compares currents, not concentrations.

7 In addition to making its infringement case impossible to prove, the prosecution history  
8 precludes Pharma Tech from using the so-called “doctrine of equivalents” to prove its case. That  
9 doctrine allows a plaintiff to argue that an accused device operates in a way that is similar or  
10 equivalent to the patent claims. But because of the prosecution history, Pharma Tech must prove  
11 that the LifeScan system does *literally*—exactly—what the patent claims. Indeed, in correspondence  
12 with LifeScan before the filing of this motion, Pharma Tech abandoned any reliance on the doctrine  
13 of equivalents and confirmed that its case must be premised on literal infringement alone.

14 The LifeScan meters do not literally infringe the asserted patents because they work in a way  
15 that is the opposite of the patent claims. They compare electric current, not analyte concentration.  
16 This is not a matter of proof at trial. Rather, the Complaint itself confirms that the LifeScan meter  
17 compares currents, not concentrations, and so does not infringe those patents. Moreover, as the  
18 public record of the previous litigation between LifeScan and Pharma Tech shows, LifeScan proved  
19 as an element of that case that the LifeScan meter operates by comparing currents, not  
20 concentrations. ***Pharma Tech did not dispute that proof and it was accepted by the district court in***  
21 ***California.*** Now, in correspondence between the parties before the filing of this motion to dismiss,  
22 Pharma Tech has abandoned any contention that the algorithm controlling the operation of  
23 LifeScan’s meters compares concentrations and thereby infringes the asserted patents. Pharma Tech  
24 pins its argument for avoiding dismissal on the hope that the algorithm has changed at some point in  
25 time. This does not make Pharma Tech’s claim plausible, or even likely.

26 There are many other problems with the case that Pharma Tech has pleaded, going both to  
27 the validity of its asserted patents and the other elements of its infringement case. For present  
28 purposes, however, those issues can be set aside. The Complaint should be dismissed under *Iqbal*

1 and *Twombly* because it does not provide a plausible basis for concluding that LifeScan's OneTouch  
2 system compares analyte concentrations, as required by the '069 and '411 patents, rather than  
3 currents.

#### 4 **I. Background**

##### 5 **A. Blood Glucose Monitoring**

6 This case involves meters and disposable test strips that are used by diabetics to monitor their  
7 blood glucose levels. This monitoring helps detect hypoglycemia (low blood glucose) or  
8 hyperglycemia (high blood glucose), which can lead to serious complications if untreated. Blood  
9 glucose testing typically is done by the individual, at home, several times each day. The testing  
10 entails pricking a fingertip with a lancet and touching the resulting blood drop to the end of a  
11 disposable test strip inserted in a meter. It is one of the most important things diabetics can do to  
12 ensure their health and avoid long-term complications.

##### 13 **B. The Parties and Their Respective Products**

14 LifeScan is the worldwide leader in the market for glucose monitoring systems. Defendants  
15 LifeScan, Inc. and LifeScan Scotland, Ltd. are subsidiaries of Johnson & Johnson. LifeScan  
16 Scotland, Ltd. owns U.S. Patent No. 7,250,105 (the '105 patent), which is quoted in claim charts that  
17 are Exhibits to the Complaint. The exclusive licensee of the '105 patent is LifeScan, Inc., which  
18 makes and sells the OneTouch Ultra glucose monitoring system that is accused of infringing the  
19 '069 and '411 patents. The '105 patent provides a method for assuring that the blood glucose  
20 readings provided by the meter are correct. In the method of the '105 patent, after a blood sample is  
21 inserted in the meter (via a test strip), two separate electrodes take two separate measurements of the  
22 electric current generated by the sample. If those two measurements are within a fixed amount of  
23 each other, the system deems the reading accurate and then, and only then, combines the currents  
24 and converts them into a single glucose measurement, which is displayed on the meter. LifeScan  
25 markets this method as its "DoubleSure" technology.

26 The Plaintiffs are Pharma Tech Solutions, Inc. and Decision IT Corp. (collectively,  
27 "Pharma Tech"). Pharma Tech Solutions, Inc. promotes and sells a test strip known as the GenStrip  
28 for use with OneTouch meters as a substitute for LifeScan's OneTouch test strips. Its sales have

1 been de minimis, both before and after the FDA issued a “Safety Communication” warning to  
2 consumers to stop using the GenStrip on April 29, 2014.<sup>1</sup> The FDA letter, directed to “[p]eople with  
3 type I and type II diabetes,” advised them to “stop using GenStrip Blood Glucose Test Strips  
4 because the strips may report incorrect blood glucose levels.”

5 **C. The ‘069 and ‘411 Patents**

6 In this case, Pharma Tech accuses LifeScan of infringing the ‘069 and ‘411 patents.  
7 According to the Annual Report of DDI, Pharma Tech’s parent corporation, DDI purchased those  
8 patents in 2015 for \$250,000, and then entered into a contingent fee arrangement with  
9 Pharma Tech’s attorneys to bring this case. The entity that sold the ‘069 and ‘411 patents to DDI  
10 (Tall Oak Ventures LLC) had tried for years to find a buyer for those patents, without success. The  
11 sale to DDI was consummated only as the patents were expiring. If this case is not dismissed,  
12 LifeScan will prove these facts.

13 The ‘069 and ‘411 patents have the same inventors. The ‘411 patent is a continuation of the  
14 ‘069 patent. Both patents have the same written description or “specification.” Because both  
15 patents have expired, injunctive relief is not available in this case. During the lifetime of these  
16 patents, there is no public record that they were ever enforced against anyone and no public record  
17 that they ever resulted in any commercial product. That is, during the lifetime of the patents, there is  
18 no public record that they generated one dollar of income to their owners. That is undoubtedly  
19 because the patents are extremely narrow and cover a device that is not sold in the commercial  
20 marketplace.

21 The common specification of the ‘069 and ‘411 patents describes a system for measuring  
22 blood glucose levels. Many of the features of that system were known in the prior art (that is, in  
23 prior publications in the science of glucose measurement). The system uses a “sensor,” i.e., a test  
24 strip with a reagent layer, which is “inserted into [a] meter ....” Cplt., Ex. A at col. 4:18–23. After  
25 the sensor is wetted by a “sample fluid,” e.g., blood, the meter “imposes a known potential across the  
26 [sensor’s] electrodes and measures the resulting ... current at specific time points ....” *Id.* at col.

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27 <sup>1</sup> Shasta Technologies GenStrip Blood Glucose Test Strips May Report False Results: FDA Safety  
28 Communication, <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm395180.htm> (last visited  
Aug. 10, 2016).

1 4:21–38. “Measurements ... of the current ... [are] proportional to the glucose concentration in the  
2 sample.” *Id.* at col. 3:36–39.

3 Unlike LifeScan’s commercial OneTouch Ultra meter and test strip system, however, the  
4 system of the ‘069 and ‘411 patents then converts the current readings into two separate glucose  
5 concentrations and compares those concentration measurements. The patents explain: the  
6 “[measured] **current** values are ... used to calculate the **analyte [e.g., glucose] concentration** which  
7 is then displayed.” *Id.* at col. 4:38–39. (An “analyte” is a “component that is being measured in a  
8 chemical analysis.” MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS at 93 (6th  
9 ed. 2003)). Results for glucose concentration “can then be calculated at the different time points and  
10 compared.” *Id.* at col. 4:45–57. “In a system that is operating correctly, the results should agree  
11 within reasonable limits. .... Results outside the acceptable limits would indicate some problem  
12 with the system.” *Id.*

13 The prosecution history of the ‘069 and ‘411 patents, which is subject to judicial notice,  
14 shows that during prosecution the patent Examiner repeatedly rejected the inventors’ initial broad  
15 claims as anticipated and/or obvious in view of prior art on blood glucose testing. That is, the patent  
16 Examiner repeatedly expressed the view that there was nothing inventive about the applicants’  
17 proposed claims. To overcome those rejections, the inventors amended their claims to make them  
18 extremely narrow—fundamentally different from the claims of LifeScan’s ‘105 patent and  
19 applicable to no commercial device. As amended, the claims require comparing separate  
20 measurements of **analyte concentration**. The applicants told the PTO and the public that this feature  
21 makes their invention different from the prior art and it is an essential element of any infringement  
22 case. *See* pages 21–22, *infra*.

23 As a result, the claims in the ‘069 and ‘411 patents all require converting separate  
24 measurements of current into two or more separate measurements of analyte (e.g., glucose)  
25 concentration, and comparing these separate measurements of analyte concentration to confirm that  
26 they are within a prescribed percentage of one another. Thus, claim 1 of the ‘069 patent, which  
27 LifeScan is alleged to infringe (Cplt., ¶ 16), requires, among other things, a “microprocessor means”  
28 for: (1) “converting” two or more current readings into separate “**analyte concentration**

measurement[s],” Cplt., Ex. B at col. 13:48–55, and then (2) “comparing” those “**analyte concentration** measurement[s]” to “confirm that they are within a prescribed percentage of each other,” *id.* at col. 13:55–59 (all emphasis added). The other independent claims of the ‘069 patent include the same requirements, using the same language, *see id.* at col. 14:39–51 (claim 4) or substantially identical language, *see id.* at col. 15:21–32 (claim 5), 16:28–41 (claim 6). The independent claims of the ‘411 patent also require converting two or more current readings into “**analyte concentration** measurement[s]” and then comparing these “**analyte concentration**” measurements. Cplt., Ex. A at col 13:40–50 (claim 1), 14:26–37 (claim 4), 15:5–19 (claim 7), 16:17–29 (claim 8) (emphasis added).

The only other claims in the ‘069 and ‘411 patents are dependent claims, which incorporate the limitations of the independent claims. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989) (“[A] dependent claim includes all the limitations of the claim from which it depends.”). As a consequence, every single claim of the two asserted patents requires a comparison of analyte concentrations—unlike the comparison of currents that is done by LifeScan’s OneTouch Ultra system and required by the ‘105 patent.

#### **D. LifeScan’s OneTouch Ultra System**

LifeScan’s OneTouch system never creates or compares separate measurements of “analyte concentration,” as required by the claims of the ‘069 and ‘411 patents. Instead, as described in LifeScan’s ‘105 patent (which is marked on the system’s packaging), the OneTouch system compares electric **currents** measured at two working electrodes to see if those **currents** are within a specified range of each other. Although currents are proportional to analyte concentrations, they are not the same—as the inventors of the Pharma Tech patents recognized in prosecuting their claims in the PTO—and they are therefore outside the scope of the asserted patents. As a result, the OneTouch system never performs the “converting” and “comparing” steps using analyte concentrations, as required by the claims of the ‘069 and ‘411 patents. Rather, it computes glucose concentration only after making a comparison of currents, and then computes a single glucose concentration, which it does not compare to anything.



1           **E.       Pharma Tech’s Complaint and the Accompanying Claim Charts**

2           The Complaint alleges in conclusory fashion that LifeScan’s OneTouch test strips and meters  
3 infringe both literally and under the doctrine of equivalents “at least Claim 1 of the ‘069 Patent” and  
4 “at least Claim 4 of the ‘411 Patent.” Cplt., ¶¶ 16, 20. In correspondence with LifeScan before the  
5 filing of this motion, Pharma Tech recognized that it has no colorable claim under the doctrine of  
6 equivalents and so has abandoned that claim. It cannot plausibly allege literal infringement either.

7           Claim charts attached to the Complaint as Exhibit C (for the ‘069 patent) and Exhibit D (for  
8 the ‘411 patent) “reflect[] Plaintiffs’ allegations [of literal infringement].” Cplt., ¶¶ 13–14. These  
9 claim charts provide additional information, but do not provide a plausible basis for asserting that the  
10 OneTouch system literally converts separate current readings into separate measurements of *analyte*  
11 *concentration*, and then compares those separate measurements of *analyte concentration*, as  
12 required by the claims of the ‘069 and ‘411 patents. Indeed, the claim charts contradict those  
13 allegations.

14           In addressing the “converting” and “comparing” limitations of the ‘069 and ‘411 claims,  
15 Pharma Tech’s claim charts rely on two items of evidence. Both are discussed below.

16           **1.       Pharma Tech’s Reliance on the ‘105 Patent**

17           Pharma Tech’s claim charts rely on the following table and text:  
18  
19  
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28

TABLE 1

Volume μL	Working 1: μA	Working 2: μA	% Difference	Error checked	No error check
1	7.07	0.00	-706800		7.07
1	6.94	5.98	-16.2175732		12.92
1	5.53	0.01	-92050		5.54
1	6.99	7.09	1.42393909	14.09	14.09
1	7.34	7.02	-4.59016393	14.35	14.35
1	7.16	6.79	-5.49742078	13.94	13.94
1	7.01	3.47	-102.13441		10.48
1	7.07	5.69	-24.2578605		12.77
1.2	7.18	4.54	-58.2286847		11.72
1.2	7.00	6.78	-3.35055351	13.78	13.78
1.2	7.09	1.79	-297.032475		8.88
1.2	6.31	0.00	-157550		6.31
1.2	6.78	6.79	0.11788977	13.56	13.56
1.2	6.95	6.59	-5.4029443	13.53	13.53
1.2	6.62	6.28	-5.36795158	12.89	12.89
1.2	7.23	3.78	-91.2721502		11.01
1.4	7.16	6.90	-3.76811594	14.06	14.06
1.4	7.14	6.94	-2.88184438	14.08	14.08
1.4	7.17	7.02	-2.13675214	14.19	14.19
1.4	7.02	6.01	-1.5918958	13.93	13.93
1.4	6.95	6.91	-0.5788712	13.86	13.86
1.4	6.93	6.88	-0.72674419	13.81	13.81
1.4	7.09	6.92	-2.4566474	14.01	14.01
1.4	7.25	7.40	2.02702703	14.65	14.65

Sum of current  
readings used for  
conversion to  
analyte  
concentrations

Source: U.S. Patent 7,250,105.

Per the '105 patent: "In the second half of the test the two currents were first compared. Only if they differed by less than 10% were they then added together and put forward as valid results." Col. 5, lns. 46-48.

Cplt., Ex. C at 19, Ex. D at 16. The "[s]ource" for this Table (*id.*) is LifeScan's '105 patent,<sup>2</sup> which is Ex. 1 to this motion.<sup>3</sup> The red boxes and red text above were added by Pharma Tech. By relying on the '105 patent in its claim charts, Pharma Tech acknowledges that the OneTouch system practices the teachings of the '105 patent.

Table 1 and the above text contradict Pharma Tech's allegations of literal infringement by indicating (correctly) that the '105 system compares **currents**, not **analyte concentrations**: "[T]he two **currents** were first compared." Cplt., Ex. C at 19 (quoting the '105 patent, col. 5:46-48) (emphasis added); Cplt., Ex. D at 16 (same). Similarly, the text in red, added by Pharma Tech, states that the "[s]um of **current** readings [is] used for conversion to analyte concentrations." Cplt., Ex. C at 19 (emphasis added); Cplt., Ex. D at 16 (same). Nothing in this Table or text supports an

<sup>2</sup> Table 1 above actually is excerpted from a longer version of the same table that appears in the '105 patent at col. 6:7-49.

<sup>3</sup> Unless otherwise indicated, "Ex. \_\_\_" refers to Exhibits to the Declaration of Anthony DeCinque.

1 assertion that the OneTouch system creates and compares separate measurements of *analyte*  
 2 *concentration*, as required by the ‘069 and ‘411 patents.

3 The ‘105 patent describes Table 1 as showing “[t]he *current* measured at each working  
 4 sensor part [which was] measured and recorded.” Ex. 1, at col. 5:40–42. “For the first part of the  
 5 test the two *currents* were simply added together ....” *Id.* at col. 5:43–45. In the second half of the  
 6 test the two *currents* were first compared. Only if they different by less than 10% were they then  
 7 added together and put forward as valid results.” *Id.* at col. 5:46–48 (all emphasis added). As  
 8 explained in the ‘105 patent’s specification, the *current* generated at the working electrodes “is  
 9 proportional to ... the *concentration* of glucose in the sample,” *id.* at col. 1:33–36, but they are not  
 10 the same thing.

11 Other passages in the ‘105 patent are to the same effect. The ‘105 patent consistently  
 12 describes comparisons of measurements of current (not analyte concentration). For example, it  
 13 states that “the *electric current* generated at each working sensor part is measured and the two  
 14 measurements are compared. If they differ by more than 10% an error message is displayed on the  
 15 measuring device and the test must be repeated. If they are within 10% of each other however, the  
 16 currents are added together in the device and are converted to a glucose level which is displayed on  
 17 an LCD.” *Id.* at col. 5:26–33 (emphasis added).

18 Nothing in Table 1—or anywhere else in the ‘105 patent—provides a plausible basis for  
 19 asserting that the OneTouch system converts separate measurements of electric current into  
 20 measurements of analyte (e.g., glucose) concentration and compares separate measurements of  
 21 analyte concentration, as required by the claims of the ‘069 and ‘411 patents. To the contrary, these  
 22 sources—cited and relied upon in the Complaint—establish that the OneTouch system, the  
 23 commercial embodiment of the ‘105 patent, works by comparing currents, not concentrations.

## 24 **2. Pharma Tech’s Reliance on the “Dear Customer” Email**

25 Pharma Tech also relies on a portion of a non-technical Customer Service email that is  
 26 reproduced below, with red underlining that Pharma Tech added:  
 27  
 28

Dear LifeScan Customer:

Thank you for taking the time to write to us. In regard to your inquiry, the OneTouch Ultra Test Strip uses patented DoubleSure technology that **automatically conducts two separate glucose measurements on each blood sample for accuracy** (*their emphasis*). When glucose in a blood sample reacts with the glucose oxidase enzyme in the OneTouch Ultra Test Strip, electrons are released and carried by a mediator to two electrodes. The electrodes each measure the flow of electrons separately. This allows two measurements to be compared and checked, leading to accurate glucose results. If a significant difference between the two measurements is detected, the OneTouch Meter recognizes there is a problem and an error message is generated.

This is not a new feature of the OneTouch Ultra Test Strip. This feature has always contributed to the proven accuracy and performance of the OneTouch Ultra blood glucose monitoring systems. We are choosing to emphasize this feature to consumers and HCPs now to better explain how the OneTouch Ultra Test Strip delivers the proven accuracy and performance consumers have enjoyed over the past 7 years.

Cplt., Ex. C at 14, 18 (red underlining added by Pharma Tech), Ex. D at 9, 15 (same).

Pharma Tech focusses on a sentence fragment that the OneTouch system “conducts two separate glucose measurements,” but the quoted sentence in its entirety makes clear that the measurements taken are actually those required by the “*patented DoubleSure technology*”—patented in the ‘105 patent—and therefore are actually two separate measurements of electric current, not measurements of glucose concentration. *Id.* The paragraph makes that even clearer as it continues:

When glucose in a blood sample reacts with the glucose oxidase enzyme ..., *electrons are released* and carried by a mediator to two electrodes. The electrodes each *measure the flow of electrons separately* ... allow[ing] two measurements to be compared and checked, leading to accurate glucose results. If a significant difference between the two measurements is detected, the OneTouch Meter recognizes there is a problem and an error message is generated.

*Id.* (emphasis added). The only plausible reading of this non-technical paragraph, particularly in light of the technical contents of the ‘105 patent itself, is that the OneTouch system practices the “patented ... technology” of the ‘105 patent by computing and comparing “the flow of electrons [i.e., the current] separately.” This contradicts Pharma Tech’s allegations of literal infringement.

**F. Undisputed Evidence from the California Case Contradicts Pharma Tech's Allegations**

The parties previously were adversaries in a case captioned *LifeScan, Inc. v. PharmaTech Solutions, Inc.*, Case No. 11-cv-4494 (N.D. Cal.) (the “California Case”). In the California Case, LifeScan asserted, among other things, that Pharma Tech induced customers to infringe the ‘105 patent by using Pharma Tech’s GenStrip test strips with LifeScan’s OneTouch meter. By relying on the ‘105 patent in the claim charts attached to its Complaint here, *see* Cplt., Ex. C at 19, Ex. D at 16, Pharma Tech agrees that the OneTouch system is a commercial embodiment of the ‘105 patent. (And, indeed, the ‘105 patent is marked on the packaging of the One Touch meter, as LifeScan alleged in the California Case. Ex. 2, at ¶ 26 (Amended Complaint)).

When LifeScan moved for a preliminary injunction in the California Case, it needed to show that using Pharma Tech’s GenStrip test strips with a OneTouch Ultra meter meets every claim limitation of the ‘105 patent, including the limitations that require (in the meter) “measuring an electric **current** at each working sensor” and “comparing the electric **current** from each of the working sensor parts ....” Ex. 1 at col. 7:12–col. 8:2 (emphasis added). LifeScan proved this through an expert declaration from Dr. Mark Meyerhoff, who explained that “[a] review of LifeScan documentation indicates that a **comparison of currents** between the two working sensor parts occurs when a test strip is used with OneTouch® Ultra® meters ....” Ex. 3 at ¶¶ 39–40 (emphasis added). The expert declaration that Pharma Tech submitted in response (Ex. 4) did not dispute this.<sup>4</sup> Thus, in finding that LifeScan had proved a likelihood that it would prevail on its infringement claim, the district court stated that the parties “appear[ed] to agree” that the OneTouch meter practices these elements of the claims of the ‘105 patent. *LifeScan, Inc. v. Shasta Techs., LLC*, 933 F. Supp. 2d 1243, 1254 (N.D. Cal. 2013), *rev’d on other grounds sub nom. LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361 (Fed. Cir. 2013). The undisputed fact that the OneTouch meter compares **currents** (not **concentrations**) was essential to the district court’s determination that

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<sup>4</sup> The Court may take judicial notice of Dr. Meyerhoff’s declaration in the California Case and the responsive declaration by Pharma Tech’s expert. *See Reyn’s Pasta Bella, LLC v. Visa LLC*, 442 F.3d 741, 746 n.6 (9th Cir. 2006) (courts “may take judicial notice of court filings,” including “documents ... filed under seal”); *Olga C. v. County of Santa Clara*, No. 5:15-cv-01691, 2015 U.S. Dist. LEXIS 128679, \*12 n.2 (N.D. Cal. Sept. 23, 2015) (same).

LifeScan had “demonstrated a likelihood of success on the question of infringement.” *Id.*, 933 F. Supp. 2d at 1255.<sup>5</sup> Pharma Tech never disputed this fact, either in the district court or on appeal.<sup>6</sup>

### **G. The OneTouch Algorithm Refutes Pharma Tech’s Allegations**

Before filing this motion, LifeScan wrote to Pharma Tech and demonstrated that the algorithm controlling the LifeScan meter did not literally infringe the asserted patents and that Pharma Tech could not assert infringement under the doctrine of equivalents. In response, Pharma Tech did not dispute either demonstration.

In particular, with respect to literal infringement, LifeScan provided the algorithm that governs the operation of the OneTouch system, the same algorithm that LifeScan had provided to Pharma Tech earlier, in discovery in the California Case. *See* Ex. 5. LifeScan urged Pharma Tech to voluntarily dismiss this case because there is no plausible basis for alleging infringement of the ‘069 and ‘411 patents.

Pharma Tech’s experts had a month to review the materials LifeScan had provided. After completing that review, Pharma Tech did not dispute that the algorithm compares currents, not concentrations. Instead, citing an imprecise public statement by a LifeScan executive about how the meter works, Pharma Tech said it wanted to take “formal discovery” to investigate the possibility that LifeScan may have “modified” the algorithm at some later point in time. Ex. 6 at 2–3. That is, Pharma Tech has acknowledged that its sole alleged good faith basis for maintaining this lawsuit is the hope that the LifeScan’s algorithm has possibly changed over time, from one that compares currents to one that compares concentrations. As LifeScan responded, again before filing this

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<sup>5</sup> The Federal Circuit reversed the grant of a preliminary injunction on other grounds, but it did not disturb the district court’s finding that the OneTouch system meets every limitation of the ‘105 patent. The Federal Circuit relied instead on the doctrine of patent exhaustion, which has no bearing on the issues here. *See LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1366–77 (Fed. Cir. 2013).

<sup>6</sup> In addition to LifeScan’s claim on the ‘105 patent, which was invalidated for reasons not germane to this dispute, LifeScan asserted two other patents against Pharma Tech. The district court denied Pharma Tech’s motion seeking to invalidate those patents. *See* ECF No. 536 in the California Case, No. 11-cv-4494 (N.D. Cal. Mar. 8, 2016). After the district court rejected Pharma Tech’s invalidity arguments and after Pharma Tech offered no infringement defense, the case settled before summary judgment could be decided against Pharma Tech. LifeScan also asserted Lanham Act claims against Pharma Tech in a related case, in which a preliminary injunction was granted and affirmed by the Ninth Circuit. *LifeScan, Inc. v. Shasta Tech., LLC*, 551 F. App’x 935 (9th Cir. 2014). For its part, Pharma Tech asserted antitrust and Lanham Act claims against LifeScan. All of the parties’ claims were terminated by the settlement, which continued the prohibition against trademark violations by Pharma Tech.



1 motion, that did not happen. LifeScan voluntarily provided Pharma Tech with documentary  
 2 evidence and a declaration, which demonstrate that the algorithm governing the OneTouch system  
 3 has at no time compared glucose concentrations. *See* Exs. 9 and 10. The relevant technical  
 4 documents are now in Pharma Tech’s possession, and there is no support in these documents for  
 5 Pharma Tech’s allegations of infringement.

6 As a result, LifeScan is hopeful that there will be no need for a decision on this motion. It is  
 7 filing the motion, however, because the Complaint should be dismissed and LifeScan will ask the  
 8 Court to do so if Pharma Tech does not do so voluntarily.

## 9 **II. The Standard for a Motion to Dismiss Under *Iqbal* and *Twombly***

10 Even before *Iqbal* and *Twombly*, it was settled law that a complaint can be dismissed if, as is  
 11 the case here, the facts that it recites are inconsistent with its claim for relief. *Sprewell v. Golden*  
 12 *State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001) (“We have held that a plaintiff can—as Sprewell  
 13 has done here—plead himself out of a claim by including unnecessary details contrary to his  
 14 claims.”) (citing cases); *A/P Hotel, LLC v. Lehman Bros. Holdings, Inc.*, No. 2:10-cv-0720, 2010  
 15 U.S. Dist. LEXIS 129917, \*5 (D. Nev. Dec. 8, 2010) (document attached to complaint “totally  
 16 refutes” the complaint’s allegations). *Iqbal* and *Twombly* have made it even easier to dismiss a  
 17 complaint on a motion to dismiss.

18 To survive a Rule 12(b)(6) motion under *Iqbal*, 556 U.S. 662, and *Twombly*, 550 U.S. 544, a  
 19 complaint must allege “enough facts to state a claim for relief that is plausible on its face.”  
 20 *Twombly*, 550 U.S. at 570. To meet this “demanding” standard (*Eclectic Props. East, LLC v.*  
 21 *Marcus & Millchap Co.*, 751 F.3d 990, 996 (9th Cir. 2014)), a plaintiff must allege facts that add up  
 22 to “more than a sheer possibility that a defendant has acted unlawfully.” *Iqbal*, 556 U.S. at 678. The  
 23 complaint must include factual allegations that make it not merely possible, but **plausible**, that the  
 24 defendant is liable for the wrong alleged and a complaint will not pass muster unless it “include[s]  
 25 sufficient ‘factual enhancement’ to cross ‘the line between possibility and plausibility.’” *Eclectic*  
 26 *Props.*, 751 F.3d at 995 (quoting *Twombly*, 550 U.S. at 557).<sup>7</sup>

27  
 28 <sup>7</sup> Because a motion to dismiss under Rule 12(b)(6) “raises a purely procedural issue,” the applicable standards here are those articulated by Court of Appeals for the Ninth Circuit, rather than by the Federal

1 “Establishing the plausibility of a complaint’s allegations is a two-step process that is  
 2 ‘context-specific’ and ‘requires the reviewing court to draw on its judicial experience and common  
 3 sense.’” *Id.*, 751 F.3d at 995–96 (quoting *Iqbal*, 556 U.S. at 679). “First, a court should ‘identif[y]  
 4 pleadings that, because they are no more than conclusory, are not entitled to the assumption of  
 5 truth.’” *Id.*, 751 F.3d at 996 (quoting *Iqbal*, 556 U.S. at 679). “Then, a court should ‘assume the[]  
 6 veracity’ of ‘well-pleaded allegations’ and ‘determine whether they plausibly give rise to an  
 7 entitlement to relief.’” *Id.* (quoting *Iqbal*, 556 U.S. at 679). “Where a complaint pleads facts that  
 8 are merely consistent with a defendant’s liability, it stops short of the line between possibility and  
 9 plausibility of entitlement to relief.” *Id.* (quoting *Iqbal*, 556 U.S. at 678).

10 “[C]ourts must also consider [whether there is] an ‘obvious alternative explanation’ for  
 11 defendant’s behavior.” *Eclectic Props.*, 751 F.3d at 996 (quoting *Iqbal*, 556 U.S. at 682). “When  
 12 faced with two possible explanations, only one of which can be true and only one of which results in  
 13 liability, plaintiffs cannot offer allegations that are ‘merely consistent with’ their favored explanation  
 14 but also consistent with the alternative explanation.” *In re Century Aluminum Securities Litig.*, 729  
 15 F.3d 1104, 1108 (9th Cir. 2013) (citing *Iqbal*, 556 U.S. at 678). “[W]hen a defendant’s plausible  
 16 alternative explanation is so convincing that plaintiff’s explanation is implausible,” then dismissal is  
 17 appropriate. *Eclectic Props.*, 751 F.3d at 996 (quoting *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir.  
 18 2011)).

19 In applying *Iqbal* and *Twombly*, courts also must balance principles of notice pleading  
 20 against the need to prevent a plaintiff “with a largely groundless claim” from going forward where  
 21 the burdens and expense of defense “represent[] an *in terrorem* increment of settlement value.”  
 22 *Eclectic Props.*, 751 F.3d at 995 (quoting *Twombly*, 550 U.S. at 557–58); *see also id.* at 996 (courts  
 23 must consider whether it is “unfair” to “require the [defendant] to be subjected to the expense of  
 24 discovery and continued litigation.”) (quoting *Starr*, 652 F.3d at 1216).

25 The materials that can be considered on Rule 12(b)(6) motion include “the pleadings,  
 26 exhibits attached to the complaint, and matters properly subject to judicial notice,” *Manzarek v. St.*

27  
 28 Circuit. *K-Tech Telecommunications, Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1282 (Fed. Cir. 2013)  
 (citation omitted).



1 *Paul Fire & Marine Co.*, 519 F.3d 1025, 1030–31 (9th Cir. 2008), (quoting *Outdoor Media Group,*  
 2 *Inc. v. City of Beaumont*, 506 F.3d 895, 899 (9th Cir. 2007)), as well as “documents referred to in the  
 3 complaint ....” *Drieling v. Am. Exp. Co.*, 458 F.3d 942, 946 n.2 (9th Cir. 2006); *see also Shwarz v.*  
 4 *United States*, 234 F.3d 428, 435 (9th Cir. 2000).

5 Although *Iqbal* and *Twombly* now apply the same way in patent cases as in other types of  
 6 actions, this was not always the case. Before December 1, 2015, Form 18 in the Appendix to  
 7 Rule 84 of the Federal Rules of Civil Procedure provided a skeletal form pleading for patent cases,  
 8 and pleadings using that form were deemed sufficient.<sup>8</sup> However, amendments to the Federal Rules  
 9 that became effective on December 1, 2015 “abrogate[d] both Rule 84 [Fed. R. Civ. P.] and the  
 10 Appendix of Forms that Rule 84 had identified as sufficient ....” *Atlas IP, LLC v. Exelon Corp.*, No.  
 11 15 C 10746, 2016 U.S. Dist. LEXIS 64571, \*12 (N.D. Ill. May 17, 2016). The Complaint in this  
 12 case was filed on March 14, 2016—after the change abrogating Rule 84 and Form 18 became  
 13 effective. Like other types of actions, patent cases filed after December 15, 2015 are subject to  
 14 dismissal under *Iqbal* and *Twombly* if their factual allegations do not provide a plausible basis for  
 15 liability. *Atlas*, 2016 U.S. Dist. LEXIS 64571, \*12.<sup>9</sup>

16 Where dismissal is appropriate under *Iqbal* and *Twombly*, leave to amend ordinarily should  
 17 be granted. But “dismissal without leave is proper if it is clear that the complaint could not be saved  
 18 by amendment.” *Li v. Kerry*, 710 F.3d 995, 999 (9th Cir. 2013) (citation omitted).

### 19 **III. The Complaint Does Not Provide a Plausible Basis for Alleging Infringement**

#### 20 **A. The Law on Patent Infringement**

21 Determining patent infringement is a “two step inquiry.” *Tessera v. Int’l Trade Comm’n*,  
 22 646 F.3d 1357, 1364 (2011). “First, the court must construe the asserted claim .... Second, the  
 23 court must determine whether the accused product or process contains each limitation of the properly  
 24 construed claims.” *Id.* (citation omitted). If even a single claim limitation is not present, literally or

25  
 26 <sup>8</sup> See *K-Tech*, 714 F.3d at 1283–84; *R+L Carriers, Inc. v. DriverTech LLC (In re Bill of Lading Transmission & Processing Sys. Patent Litig.)*, 681 F.3d 1323, 1335 n.7 (Fed. Cir. 2013).

27 <sup>9</sup> See also *Tannerite Sports, LLC v. Jerent Enterprises, LLC*, No. 6:15-cv-00180, 2016 U.S. Dist. LEXIS  
 28 57942, \*5–15 (D. Ore. May 2, 2016); *Ruby Sands LLC v. American Nat. Bank of Tex.*, No. 2:15-cv-1955,  
 2016 U.S. Dist. LEXIS 83897, \*7–8 (E.D. Tex. June 28, 2016); *RAH Color Techs., LLC v. Ricoh USA, Inc.*,  
 No. 2:15-cv-05203, 2016 U.S. Dist. LEXIS 87871, \*3–14 (E.D. Pa. July 6, 2016).

1 by a substantial equivalent, then there is no infringement. *Id.*; *see also Wi-LAN, Inc. v. Apple, Inc.*,  
2 811 F.3d 455, 463 (Fed. Cir. 2016).

3 The first step—claim construction—is straightforward here. The ordinary and customary  
4 meaning of “analyte concentration” refers to the “relative content ... expressed in percentage by  
5 weight or by volume”<sup>10</sup> of a “specific component that is being measured in a chemical analysis.”<sup>11</sup>  
6 Nothing in the patents’ specification or prosecution history gives those terms a different meaning.  
7 The ordinary meaning accordingly applies here.<sup>12</sup> Pharma Tech does not suggest otherwise.

8 As to the second step, there are two types of infringement: literal infringement and  
9 infringement under the doctrine of equivalents. Pharma Tech has conceded that it has no basis for  
10 relying on the doctrine of equivalents, Ex. 6 at 3 n.3, although the Complaint alleges both types of  
11 infringement (at ¶¶ 16, 20).

#### 12 **B. Pharma Tech Has No Plausible Basis for Alleging Literal Infringement**

13 Literal infringement requires that every claim limitation “must be found in an accused  
14 product, exactly.” *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1319 (Fed.  
15 Cir. 2015) (citation omitted). The Complaint and the attached claim charts do not provide a  
16 plausible basis for concluding that the OneTouch system converts separate measurements of current  
17 into separate measurements of analyte concentration and then compares those separate  
18 measurements of analyte concentration, as required by the claims of the ‘069 and ‘411 patents. *See*  
19 *Atlas v. Excelon*, 2016 U.S. Dist. LEXIS 64571 (dismissing a patent infringement action under *Iqbal*  
20 and *Twombly*). Rather, the only plausible conclusion from the information properly considered on  
21 this motion to dismiss is that the OneTouch system works by comparing currents, not concentrations.

22  
23 <sup>10</sup> *See* WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY at 469 (2002) (defining “concentration” as the  
24 “relative content of a component ... expressed in percentage by weight or by volume”).

25 <sup>11</sup> *See* MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS at 93 (6th ed. 2003) (defining  
26 “analyte” as “[t]he specific component that is being measured in a chemical analysis”).

27 <sup>12</sup> *See TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1327 (Fed. Cir. 2015) (“Claim terms are generally given their  
28 plain and ordinary meanings to one of skill in the art when read in the context of the [patent] specification and  
prosecution history.... There are only two exceptions to this general rule: 1) when a patentee sets out a  
definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term  
either in the specification or during prosecution.”) (quoting *Golden Bridge Tech., Inc. v. Apple, Inc.*, 758 F.3d  
1362, 1365 (Fed. Cir. 2013)).

1 In considering a Rule 12(b)(6) motion, a court is “not required to accept as true conclusory  
 2 allegations which are contradicted by documents referred to in the complaint.” *Colony Cove Props.,*  
 3 *LLC v. City of Carson*, 640 F.3d 948, 955 (9th Cir. 2011) (quoting *Warren v. Fox Family*  
 4 *Worldwide, Inc.*, 328 F.3d 1136, 1139 (9th Cir. 2003)). Here, Pharma Tech’s allegations are  
 5 “compellingly contradicted” by the claim charts Pharma Tech attached to its Complaint. *Gonzalez v.*  
 6 *Planned Parenthood of Los Angeles*, 759 F.3d 1112, 1115 (9th Cir. 2014) (affirming dismissal under  
 7 *Iqbal*).

8 Pharma Tech’s claim charts are premised on a recognition that the OneTouch system  
 9 practices the ‘105 patent. But, as they correctly quote the ‘105 patent, the system described in that  
 10 patent compares **currents**, not **concentrations**. See Cplt., Ex. C at 19 (“In the second half of the test  
 11 the two **currents** were first compared.”) (quoting the ‘105 patent, col. 5:46–48) (emphasis added);  
 12 Cplt., Ex. D at 16 (same). This Court may consider the ‘105 patent itself in addition to the claim  
 13 charts because it is quoted in Pharma Tech’s claim charts and because it is subject to judicial notice.  
 14 See *Coinstar, Inc. v. Coinbank Automated Sys., Inc.*, 998 F. Supp. 1109, 1114 (N.D. Cal. 1998). A  
 15 review of the ‘105 patent shows that it contradicts Pharma Tech’s allegations of infringement in  
 16 numerous places and renders its allegations of infringement implausible.<sup>13</sup>

17 Pharma Tech’s claim charts contradict its infringement allegations again when they state, in  
 18 red for emphasis, that in the OneTouch system the “[s]um of **current** readings [is] used for  
 19 conversion to analyte concentrations.” Cplt., Ex. C at 19 (emphasis added), Ex. D at 16 (same). In  
 20 contrast, the claims of the ‘069 and ‘411 patents require converting two separate current readings  
 21  
 22

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23 <sup>13</sup> See, e.g., Ex. 1 at col. 5:26–33 (“After a predetermined time the **electric current** generated at each working  
 24 sensor part is measured and the two measurements are compared. If they differ by more than 10% an error  
 25 message is displayed on the measuring device and the test must be repeated. If they are within 10% of each  
 26 other however, the currents are added together in the device and are converted to a glucose level which is  
 27 displayed on an LCD.”); *id.* at col. 5:40–48 (“The **current** measured at each working sensor part was  
 28 measured and recorded.... For the first part of the test the two **currents** were simply added together .... In the  
 second half of the test the two **currents** were first compared. Only if they differed by less than 10% were they  
 then added together and put forward as valid results.”); *id.* at col.6:51–col. 8:2 (claim 1) (“The invention  
 claimed is: 1. A method of measuring the concentration of a substance in a sample liquid comprising the steps  
 of ... measuring an electric **current** at each working sensor part ... [and] comparing the electric **current** from  
 each of the working sensor parts ....”) (all emphasis added).

1 into separate concentration measurements and then comparing those separate concentration  
2 measurements.

3 Pharma Tech's infringement allegations also are contradicted by undisputed evidence in the  
4 California case, which is subject to judicial notice. *See Reyn's Pasta Bella*, 442 F.3d at 746 n.6 (9th  
5 Cir. 2006) (courts "may take judicial notice of court filings," including "documents filed under  
6 seal"). To demonstrate a likelihood of success on its motion for a preliminary injunction in the  
7 California case, LifeScan needed to show that the OneTouch meter "measure[es] an electric **current**  
8 at each working sensor part" and "compar[es] the electric **current** from each of the working sensor  
9 parts," as required by the claims of the '105 patent (Ex. 1 at col. 7:12–col. 8:2) (emphasis added).  
10 LifeScan demonstrated this through a detailed expert declaration, which said that "[a] review of  
11 LifeScan documentation indicates that a **comparison of currents** between the two working sensor  
12 parts occurs when a test strip is used with OneTouch® Ultra® meters ...." Ex. 3 at ¶¶ 39–40  
13 (emphasis added). Pharma Tech never disputed the issue and the Court found that LifeScan had  
14 established that it was likely that it would prove its infringement case. *LifeScan*, 933 F. Supp. 2d at  
15 1254. *See* page 12–13, *supra*. Pharm Tech never challenged the Court's infringement conclusion on  
16 this basis, either in the district court or on appeal.

17 All of this evidence, properly considered on this motion to dismiss, is a convincing refutation  
18 of Pharma Tech infringement case. It is rare indeed for a plaintiff to attach to its pleadings the  
19 evidence that shows that its case is baseless, and doubly rare when that plaintiff turns out already to  
20 have litigated the precise issue and conceded in that case that its current claim was baseless.

21 Against all of this, the only sliver of evidence supporting Pharma Tech's case is the  
22 imprecise snippet from the "Dear Customer" email that states—incorrectly—that the LifeScan  
23 system "automatically conducts two separate glucose measurements." But this is a lay summary, not  
24 scientific evidence. In a technical case such as this one, such lay evidence cannot begin to meet  
25 Pharma Tech's burden of proving infringement. *Centricut, LLC v. ESAB Group, Inc.*, 390 F.3d  
26 1361, 1370 (Fed. Cir. 2004). Instead, the Court's infringement inquiry is governed by scientific  
27 evidence about how the accused device "actually works." *Implicit Networks Inc. v. F5 Networks*  
28 *Inc.*, 2013 U.S. Dist. LEXIS 34984, \*46 (N.D. Cal. Mar. 13, 2013). *See also I.E.E. Int'l Elecs. &*

1 *Eng’g, S.A. v. TK Holdings Inc.*, 54 F. Supp. 3d 776, 823 (E.D. Mich. 2014) (plaintiff must prove  
2 how device “actually operates”).

3 More important, in the context of this motion to dismiss, the imprecision in the email is both  
4 understandable and clear, and thus does not suffice to make Pharma Tech’s case plausible. As  
5 LifeScan’s ‘105 patent and Pharma Tech’s ‘069 and ‘411 patents all confirm, glucose concentration  
6 is directly proportional to current. For that reason, it is understandable that the concentration and  
7 current would be used interchangeably for a lay audience. Moreover, the email makes clear how the  
8 LifeScan meter actually works. It states affirmatively that the OneTouch system practices the  
9 “**patented DoubleSure technology**,” a clear reference to LifeScan’s ‘105 patent, in which “**electrons**  
10 **are released** and carried by a mediator to two electrodes” that “each **measure the flow of electrons**  
11 **separately** ... allow[ing] two [current] measurements to be compared and checked,” Cplt., Ex. C at  
12 18 (emphasis added), Ex. D at 15 (same). All of this is a description of what the meter actually does.  
13 It compares currents, not glucose concentrations, as the ‘105 patent requires. Laid against the  
14 technical evidence cited in the Complaint and in the previous proceeding, this email does not make  
15 Pharma Tech’s case plausible.

16 In the end, it is the meter algorithm that matters, and Pharma Tech and its experts reviewed  
17 the algorithm with care in the California case and accepted LifeScan’s showing that the OneTouch  
18 meter compares currents, not concentrations. Pharma Tech then relied on the ‘105 patent, which is  
19 the basis for the meter algorithm, in framing the Complaint in this case. On this motion, the Court  
20 must consider whether there is an “obvious alternative explanation” for defendant’s behavior.”  
21 *Eclectic Props.*, 751 F.3d at 996 (quoting *Iqbal*, 556 U.S. at 682). The obvious alternative  
22 explanation for the operation of LifeScan’s meter is that it compares currents, not concentrations, as  
23 the ‘105 patent requires, as its packaging states, as Pharma Tech’s Complaint demonstrates and as  
24 Pharma Tech agreed in the California litigation. Indeed, in light of the allegations in the Complaint  
25 and the evidence of which the Court can take judicial notice, that is the only plausible explanation  
26 for how the meter works. “[W]hen a defendant’s plausible alternative explanation is so convincing  
27 that plaintiff’s explanation is implausible,” then dismissal is appropriate. *Eclectic Props.*, 751 F.3d  
28 at 996 (quoting *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011)).

1 In short, Pharma Tech’s allegations of literal infringement are contradicted, again and again,  
 2 by evidence on which Pharma Tech relies and which it has examined with care. Those allegations  
 3 are not just “largely groundless,” *Eclectic Props.*, 751 F.3d at 995—they are completely groundless.  
 4 This case, like *Atlas v. Exelon*, is “a hopeless lawsuit of precisely the sort that the last decade’s  
 5 interpretation of and amendments to the [Federal] Rules were intended to dispose of quickly and  
 6 even to deter outright.” *Id.*, 2016 U.S. Dist. LEXIS 64571, \*16 (dismissing a patent infringement  
 7 claim under *Iqbal* and *Twombly*). Pharma Tech has pleaded itself out of court.

### 8 C. Pharma Tech is Barred from Relying on the Doctrine of Equivalents

9 The doctrine of equivalents may apply where an accused product or method does not have  
 10 every limitation of the patent’s claims exactly, but “contains an equivalent for each limitation not  
 11 literally satisfied.” *Wi-LAN*, 811 F.3d at 463. Pharma Tech alleged infringement under the doctrine  
 12 of equivalents in its Complaint, *see* Cplt., ¶¶ 16, 20, but it has now admitted that it cannot rely on the  
 13 doctrine of equivalents here. Ex. 6 at 3 n.3.

14 The doctrine of equivalents is unavailable because of amendment-based estoppel under *Festo*  
 15 *Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722 (2002). Under *Festo*,  
 16 amendments to claims during patent prosecution for reasons of patentability create a presumption  
 17 that the doctrine of equivalents is not available for any claim limitation that was added or changed  
 18 by amendment. *Id.*, 535 U.S. at 736. The rationale is that “[a] patentee who narrows a claim as a  
 19 condition for obtaining a patent disavows his claim to the broader subject matter ....” *Id.*, 535 U.S.  
 20 at 736–37. A patent owner can only overcome the *Festo* presumption in rare circumstances, by  
 21 establishing one of three exceptions identified in *Festo*, 535 U.S. at 750–41. *See Integrated Tech.*  
 22 *Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1356 (Fed. Cir. 2013).

23 The *Festo* presumption applies here because the relevant claim limitations were added by  
 24 amendment during prosecution to overcome rejections based on the prior art. Those amendments,  
 25 and the applicants’ explanation of the reasons for those amendments, are part of the prosecution  
 26 histories of the ‘069 and ‘411 patents. (The relevant prosecution history is summarized in Ex. 5.)  
 27 The prosecution histories are an “undisputed public record of proceedings in the Patent and  
 28 Trademark Office,” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en

1 banc) (internal quotation omitted), *aff'd*, 517 U.S. 370 (1996), and are subject to judicial notice.  
2 *Johnstech Int'l Corp. v. JF Microtech. SDN BHD*, Case No. 14-cv-02864, 2016 U.S. Dist. LEXIS  
3 19361, \*17–18 n.3 (N.D. Cal. Feb. 17, 2016) (citing *Standard Havens Prods., Inc. v. Gencor Indus.,*  
4 *Inc.*, 897 F.2d 511, 514 n.3 (Fed. Cir. 1990)).

5 The prosecution history shows that during prosecution the patent Examiner repeatedly  
6 rejected the applicants' claims in view of the prior art. In response, the applicants amended their  
7 claims to require converting separate measurements of electric current into analyte **concentrations**  
8 and then comparing two analyte **concentrations** with one another, and then told the Patent Office  
9 and the public that the claims, as amended, avoided the prior art. Amending the claims to avoid  
10 prior art, as the applicants did here, is "the classic basis for the application of prosecution history  
11 estoppel." *Pioneer Magnetics, Inc. v. Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003). Because  
12 Pharma Tech cannot show that any of the *Festo* exceptions applies, *see Integrated Tech.*, 734 F.3d at  
13 1356, it is barred by prosecution history estoppel from relying on the doctrine of equivalents.<sup>14</sup>

## 14 CONCLUSION

15 This Court should grant LifeScan's motion to dismiss the Complaint.<sup>15</sup>  
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26 <sup>14</sup> Argument-based estoppel, which is not addressed in this brief, provides a separate and independent reason  
27 why Pharma Tech is barred from relying on the doctrine of equivalents. *See Pods, Inc. v. Porta-Star, Inc.*,  
484 F.3d 1359, 1367–68 (Fed. Cir. 2007).

28 <sup>15</sup> LifeScan reserves its right to seek fees and costs because this is an exceptional case under 35 U.S.C. § 285.  
*See Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 134 S. Ct. 1749 (2014).



1 Dated: August 15, 2016

2 SNELL & WILMER L.L.P.

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**CERTIFICATE OF SERVICE**

I, the undersigned, declare under penalty of perjury that the foregoing **Defendants' Motion to Dismiss the Complaint Under Rule 12(b)(6)** was electronically filed with the Clerk of the Court using the CM/ECF service. All parties to this case are registered with the CM/ECF service, which will provide copies to all counsel of record.

/s/ Anthony DeCinque  
Anthony DeCinque